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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,909	12/16/2005	Robert Frigg	8932-1178-999	3108

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EXAMINER	
WOODALL, NICHOLAS W	
ART UNIT	PAPER NUMBER
3733	

MAIL DATE	DELIVERY MODE
07/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,909	FRIGG ET AL.	
	Examiner	Art Unit	
	Nicholas Woodall	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to applicant's amendment received on 05/14/2007.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 19 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durham (U.S. Patent 5,032,125).

Regarding claims 19 and 37, Durham discloses a device comprising an intramedullary pin, a bone fixation element, a sliding sleeve, and a locking mechanism. The intramedullary rod includes a first longitudinal axis, a proximal portion, a distal portion, and at least one transverse opening through the proximal portion of the pin. The transverse opening forms an oblique angle with the first longitudinal axis of the pin. The bone fixation element includes a second longitudinal axis, a first end, a second end, and a shaft. The sliding sleeve includes a central bore, an interior profile surface, and an exterior profile surface having at least a portion with a non-circular cross-section. Durham fails to disclose the interior surface profile of the sliding sleeve being configured to permit the free rotation of the bone fixation device relative to the sleeve. Durham does teach that the interior surface profile of the sliding sleeve may include flat surfaces, but that is a preferred embodiment disclosed by Durham and not necessary for the invention to operate properly. Therefore, if the flat surfaces were to be omitted

the interior surface profile of the sliding sleeve could have a circular cross-section, which would permit the bone fixation element to rotate freely relative to the sliding sleeve. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the interior profile of the sliding sleeve of Durham with a circular cross-section, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a interior surface profile in a sliding sleeve. In re Dailey and Eilers, 149 USPQ 47 (1966).

4. Claims 19-25, 27, 31, 34-38, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durham (U.S. Patent 5,032,125) in view of Lawes (U.S Patent 5,454,813).

Regarding claims 19 and 37, Durham discloses a device comprising an intramedullary pin, a bone fixation element, a sliding sleeve, and a locking mechanism as discussed above. Regarding claims 20 and 38, Durham discloses a device wherein the bone fixation device, sliding sleeve, and the locking mechanism are capable of being inserted through the transverse opening while assembled. Regarding claims 21 and 22, Durham discloses a bone fixation element further including a threaded longitudinal bore at the second end of the element. Regarding claim 23, Durham discloses a device wherein the locking mechanism is a fixing screw having a screw head has a diameter larger than the diameter of the threaded shank. Regarding claim 24, Durham discloses a device wherein the outside thread of the fixing screw corresponds to the threaded bore of the bone fixation element. Regarding claim 25,

Durham discloses a device wherein the bone fixation element is axially fixed relative to the sliding sleeve. Regarding claim 27, Durham discloses a device wherein the rear end of the sliding sleeve extends past the second end of the bone fixation device at least 0.01 mm. Regarding claim 31, Durham discloses a device wherein the first end of the bone fixation element includes a screw thread. Regarding claim 34, Durham discloses a device wherein the locking mechanism is capable of limiting the axial displacement of the sliding sleeve relative to the intramedullary pin. Regarding claims 35 and 40, Durham discloses a device Durham discloses a device wherein the bone fixation element is a screw. With regard the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Durham, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. Kalman v. Kimberly Clark Corp., 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987). Durham fails to disclose the transverse bore of the intramedullary pin having a non-circular cross-section (claims 19 and 37) and the exterior profile of the sliding sleeve having a cross-section complimentary to the cross-section of the transverse bore (claim 37). Lawes teaches a device wherein the cross-section of a transverse bore is non-circular and

complimentary to the exterior profile of a sliding sleeve in order to prevent rotation of the sliding sleeve relative to a intramedullary pin and to allow the sleeve to slide axially within the transverse bore. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Durham with a transverse bore having a non-circlular cross-section that is complimentary to the exterior profile of the sliding sleeve in view of Lawes in order to prevent rotation of the sliding sleeve relative to a intramedullary pin and to allow the sleeve to slide axially within the transverse bore.

5. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Durham (U.S. Patent 5,032,125) in view of Lawes (U.S Patent 5,454,813) further in view of Bramlet (U.S. Patent 6,648,889).

Regarding claim 27, the combination of Durham and Lawes discloses the invention as claimed except for the bone fixation element having a first annular groove and the internal surface of the sliding sleeve having a second annular groove, which are engaged by a ring element. Bramlet teaches a device that includes a nail element with a bore and a locking element with annular groove, which are engaged by a ring element in order to detent the axial movement of the locking element in the bore of the nail element (column 8 lines 32-53). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the sleeve and bone fixation element of Durham modified by Lawes with annular grooves and a ring element in view of Bramlet in order to detent axial movement of the bone fixation element in the sleeve.

6. Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durham (U.S. Patent 5,032,125) in view of Lawes (U.S Patent 5,454,813) further in view of Fixel (U.S. Patent 4,432,358).

Regarding claims 28 and 29, the combination of Durham and Lawes discloses the invention as claimed except for the bone fixation element comprising an externally threaded portion at the second end (claim 28) and the locking mechanism includes a nut with an internal thread (claim 29). Fixel teaches a device comprising a bone fixation element having external threads at a second end of the element and a locking mechanism including a nut having internal threads in order to engage the nut (column 3 lines 50-52) and to compress the broken portions of bone (column 2 lines 63-65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Durham modified by Lawes with a bone fixation element having external threads at the second end of the element and a locking mechanism which includes a nut with internal threads in view of Fixel in order to engage the nut and to compress the broken portions of bone.

7. Claims 30, 32, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durham (U.S. Patent 5,032,125) in view of Lawes (U.S Patent 5,454,813) further in view of Bresina (U.S. Patent 5,908,422).

Regarding claims 30, 32, and 39, the combination of Durham and Lawes discloses the invention as claimed except for the bone fixation element including a plurality of helical blades. Bresina teaches a bone fixation element comprising a plurality of helical blades in order to minimize the tendency to cut through the cancellous bone

tissue after implantation and provides the required stiffness to maintain the relative orientation of the bone fragments (column 2 lines 15-29). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Durham modified by Lawes with a bone fixation element including a plurality of helical blades in view of Bresina in order to minimize the tendency to cut through the cancellous bone tissue after implantation and provides the required stiffness to maintain the relative orientation of the bone fragments.

8. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Durham (U.S. Patent 5,032,125) in view of Lawes (U.S Patent 5,454,813) further in view of Bresina (U.S. Patent 5,908,422) further in view of Frigg (U.S. Patent 6,187,007).

Regarding claim 33, the combination of Durham, Lawes, and Bresina discloses the invention as claimed except for the helical blades having a pitch of at least 50 mm. Frigg discloses a bone fixation element wherein the helical blades have a pitch of at least 50 mm in order to not allow any torque to be transferred to the femur head (column 2 lines 4-7). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Durham modified by Lawes further modified by Bresina with a bone fixation element comprising helical blades with a pitch of at least 50 mm in view of Frigg in order to not allow any torque to be transferred to the femur head.

Response to Arguments

9. Applicant's arguments filed 05/14/2007 have been fully considered but they are not persuasive. The applicant's argument that Durham does not disclose a device

including a bone fixation element capable of freely rotating within a sleeve is not persuasive. As discussed in the previous office action, Durham discloses a device wherein the interior surface of the bore and the exterior surface of the lag screw may include complementary engaging surfaces to prevent rotation of the screw in the sleeve. However, Durham does not disclose that the prevention of rotation of the screw in the sleeve is a critical function of the device. Durham does not disclose the device would not work if the engaging surfaces were not there. Durham simply discloses the device may include the engaging surfaces to perform the function if one so desired. Therefore, if the engaging surfaces were omitted it the interior surface of the sleeve could have circular cross-section permitting the screw to rotate freely within the sleeve. Furthermore, Durham does not include the engagement structures in the first claim further providing evidence that the structures are not critical to the functionality of the device. The applicant's argument that Durham does not disclose a device with a locking mechanism capable of selectively locking the rotation of the bone fixation element relative to the sleeve when in a first position and permits free rotation of the bone fixation element relative to the sleeve in a second position is not persuasive. Durham discloses a screw (reference number 90) that is capable of performing the function of selectively locking the rotation of the bone fixation element relative to the sleeve when in a first position and permits free rotation of the bone fixation element relative to the sleeve in a second position. The first position can be interpreted as the screw being fully engaged with the bone fixation element and can no longer be tightened toward the bone fixation element, the screw is then capable of locking the rotation of the bone fixation

element in one direction relative to the sleeve. The second position can be interpreted as the screw being partially engaged with the bone fixation element, the screw is then capable of allowing free rotation of the bone fixation element in two directions relative to the sleeve. The applicant's argument that Durham does not disclose a device including a sliding sleeve is not persuasive. Durham discloses a device wherein the sleeve is capable of sliding through the transverse opening of the intramedullary pin. There are no limitations in the claims preventing the sleeve from being locked in position once slid into the transverse opening of the pin. All that is required by the claim language is a sleeve capable of sliding. The applicant's argument that the bone fixation element, sliding sleeve, and locking mechanism are not capable of being inserted through the transverse opening as a single preassembled unit is not persuasive. The bone fixation element, sliding sleeve, and locking mechanism is capable of being preassembled into a single unit and passed through the transverse opening of the pin if one so desired. Of the pieces of the Durham invention were on a table, a person would be able to preassemble the bone fixation element, sliding sleeve, and locking mechanism together and then pass them through the transverse opening of the intramedullary pin. There is no limitation in the claims stating the location of the intramedullary pin while the preassembled unit is being inserted into the transverse opening.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is 571-272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWW

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